Note for Publication

UNITED STATES DISTRICT COURT
DISTRICT OF NEW JERSEY

CURIA IP HOLDINGS, LLC, **Plaintiff,** **v.** **SALIX PHARMACEUTICALS, LTD.; SALIX PHARMACEUTICALS, INC.; BAUSCH HEALTH COMPANIES INC.; ALFASIGMA S.P.A.; and ALFASIGMA USA, INC.,** **Defendants.**	**Civil Action No. 21-19293 (ES) (JRA)** **OPINION**

SALAS, DISTRICT JUDGE

Before the Court is Defendants Salix Pharmaceuticals, Ltd., Salix Pharmaceuticals, Inc., Bausch Health Companies, Inc., Alfasigma S.P.A., and Alfasigma USA, Inc.'s motion to dismiss Plaintiff Curia IP Holdings, LLC's Complaint pursuant to Federal Rule of Civil Procedure 12(b)(6). (D.E. No. 33). The Court has considered the parties' submission and decides this matter without oral argument. *See* Fed. R. Civ. P. 78(b); L. Civ. R. 78.1(b). For the following reasons, Defendants' motion is **GRANTED**.

I. BACKGROUND

Plaintiff is the current owner and assignee of U.S. Patent Nos. 9,186,355 (the "'355 patent"), 10,556,915 (the "'915 patent"), 10,745,415 (the "'415 patent"), and 10,961,257 (the "'257 patent"). (D.E. No. 1 ("Compl.") ¶¶ 50–52). Plaintiff alleges that it filed the '355 patent application on July 26, 2013, and filed the '915 patent, the '415 patent, and the '257 patent applications on March 31, 2014. (*Id.* ¶¶ 49–52). Each patent contains claims directed to mixtures containing certain ratios of the α and β polymorphic forms of rifaximin. (*Id.* ¶ 53).

Defendants are manufacturers of pharmaceutical products. (*Id.* ¶¶ 32–42). According to Plaintiff, Defendants' product XIFAXAN® is a prescription antibiotic containing rifaximin. (*Id.* ¶ 35). Plaintiff alleges that Defendants have been selling a 200 mg dose of XIFAXAN® since July 2004 and a 550 mg dose of XIFAXAN® since May 2010. (*Id.*).

On October 25, 2021, Plaintiff filed suit against Defendants. Plaintiff claims that Defendants' sale of XIFAXAN®, specifically for those sold after November 2015, infringe the four patents referenced above. (*Id.* ¶¶ 59–94). Plaintiff also alleges that Defendants' infringement is willful, and it seeks damages and other relief. (*Id.* ¶ 95).

Defendants move to dismiss the Complaint, arguing that the Plaintiff's allegations confirm that XIFAXAN® was on sale prior to their patent applications and therefore constitutes prior art. (D.E. No. 33; *see also* D.E. No. 33-1 ("Mov. Br.") at 1–2; D.E. No. 44 ("Reply")).

II. LEGAL STANDARD

In assessing whether a complaint states a cause of action sufficient to survive dismissal under Federal Rule of Civil Procedure 12(b)(6), the Court accepts "all well-pleaded allegations as true and draw[s] all reasonable inferences in favor of the plaintiff." *City of Cambridge Ret. Sys. v. Altisource Asset Mgmt. Corp.*, 908 F.3d 872, 878 (3d Cir. 2018). "[T]hreadbare recitals of the elements of a cause of action, legal conclusions, and conclusory statements" are all disregarded. *Id.* at 878–79 (quoting *James v. City of Wilkes-Barre*, 700 F.3d 675, 681 (3d Cir. 2012)). The complaint must "contain sufficient factual matter, accepted as true, to state a claim to relief that is plausible on its face," and a claim is facially plausible when the plaintiff "pleads factual content that allows the court to draw the reasonable inference that the defendant is liable for the misconduct alleged." *Zuber v. Boscov's*, 871 F.3d 255, 258 (3d Cir. 2017) (first quoting *Santiago v.*

Warminster Twp., 629 F.3d 121, 128 (3d Cir. 2010); and then quoting *Ashcroft v. Iqbal*, 556 U.S. 662, 678 (2009)).

III. DISCUSSION

As noted, Defendants argue that Plaintiff's Complaint, as pled, admits that XIFAXAN® was manufactured and sold prior to the date of the first filed patent application. (Mov. Br. at 5). In light of that admission, Defendants argue that their product is necessarily prior art and therefore invalidates Plaintiff's four patents. (*Id.* at 6). The Court agrees.

Under 35 U.S.C. § 102(a)(1), a person may not obtain a patent if the claimed invention was "on sale[] or otherwise available to the public *before* the effective filing date of the claimed invention" (emphasis added).[1] An invention that was on sale before the filing date of the patent application is "prior art." To trigger this on-sale bar, the defendant bears the burden of satisfying two conditions, both of which must be satisfied prior to the filing date of the patents—that is, the "critical date." *Vanmoor v. Wal-Mart Stores, Inc.*, 201 F.3d 1363, 1366 (Fed. Cir. 2000) (citing *Pfaff v. Wells Elecs.*, 525 U.S. 55, 67 (1998)). First, the defendant's invention must be the subject of a commercial offer for sale, and second, the invention must be ready for patenting. *Id.* The second condition may be satisfied in at least two ways: "by proof of reduction to practice before the critical date; or by prior to the critical date the invention had prepared drawings or other descriptions of the invention that were sufficiently specific to enable a person skilled in the art to practice the invention." *Pfaff*, 525 U.S. at 66–67. Section 102(a)(1) reflects the old maxim of patent law, "that which infringes, if later, anticipates, if earlier." *Peters v. Active Mfg. Co.*, 129 U.S. 530, 537 (1889).

Courts have found that a defendant satisfies its burden under the on-sale bar based solely

[1] Section 102(b) contains exceptions that neither appear to be applicable here nor have been argued by either party.

on the plaintiff's own admissions. *See Vanmoor*, 201 F.3d at 1366; *Evans Cooling Sys. v. GMC*, 125 F.3d 1488 (Fed. Cir. 1997). For example, in *Vanmoor*, the Federal Circuit held that the plaintiff's patent was invalid because the accused product was placed on sale prior to the critical date. 201 F.3d at 1366. In *Evans Cooling*, the Federal Circuit determined that the presence of a sales offer for the accused product prior to the critical date invalidated the plaintiff's patent for the product. 125 F.3d at 1452. Although *Vanmoor* and *Evans Cooling* arose on motions for summary judgment, both courts found that the patent challenger met its burden of proving invalidity by clear and convincing evidence based solely on the patentee's allegation that the accused product infringed its patent and was on sale prior to the critical date. *Vanmoor*, 201 F.3d at 1366; *Evans Cooling*, 125 F.3d at 1451.[2]

However, an accused infringer meets its burden only if it "clearly practic[es] only that which was in the prior art, and nothing more." *Tate Access Floors v. Interface Architectural Res., Inc.*, 279 F.3d 1357, 1367 (Fed. Cir. 2002). In *Tate*, the Federal Circuit rejected the argument that prior art existed through textbook teachings on beveling, or sloping, the edges of laminate. *Id.* at 1362–63. The Federal Circuit found that these textbook teachings applied to contexts outside of the one outlined within the relevant patent. *Id.* Thus, where one can distinguish between the alleged prior art and the accused product, the plaintiff's product is not subject to the on-sale bar. *Id.* at 1367.

In its Complaint, Plaintiff alleges that the earliest patent filing date is 2013. (Compl. ¶ 49). Plaintiff also alleges that the "accused products" consist of XIFAXAN® manufactured after November 17, 2015. (*Id.* ¶ 54). According to Plaintiff, the accused products "contained only the

[2] It is worth noting that "the ultimate determination that a product was placed on sale under [35 U.S.C. § 102(b) (1994)] is a question of law, based on underlying facts." *Vanmoor*, 201 F.3d at 1366 (quoting *Ferag AG v. Quipp Inc.*, 45 F.3d 1562, 1566 (Fed. Cir. 1995)).

α polymorphic form of rifaximin at the time of manufacture," and this form "partially converts to the β polymorphic form during storage, transportation and other handling, resulting in the mixture that falls within the scope of the claims of the Curia Rifaximin Polymorphic Mixture Patents." (*Id.* ¶ 54). While Plaintiff limits the accused products to XIFAXAN® manufactured after November 17, 2015, Plaintiff does not allege that the accused products differ from XIFAXAN® manufactured before November 2015. For example, Plaintiff does not allege that the above conversion process was not possible or did not occur as early as 2004 and 2010, which is when the different doses of Defendants' product were first on sale. (*Id.* ¶ 54). Thus, it appears that the accused products, as plead in the Complaint, represent prior art.[3]

Relying on *Tate*, 279 F.3d 1357, Plaintiff argues that the Complaint alleges the accused products—the post-2015 products—are distinct from the pre-2015 products. (D.E. No. 42 ("Opp. Br.") at 7–8 & 11). However, merely because Plaintiff limits its infringement claim to post-2015 products does not mean Plaintiff alleges a distinction between pre- and post-2015 XIFAXAN®. (Compl. ¶¶ 59–94).[4] Nothing in the Complaint does so, and in fact the Complaint appears to suggest that pre- and post-2015 XIFAXAN® contained just the α polymorph. (*Id.* ¶¶ 42 & 54). As Defendants point out, "[t]here is no allegation in the [C]omplaint that the laws of nature applicable to the α form in the later-sold tablets would have applied any differently to the α form in the earlier-sold tablets." (Reply at 5).

Plaintiff argues that Defendants have not met their burden of proof: "[a]ccused infringers

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[3] As noted above, not only must the Defendants show that their product was on sale prior to the critical date, but they must also show that the product was ready for patenting. *See Pfaff*, 525 U.S. at 66. The parties do not dispute this second requirement, and it appears that it is satisfied based on the Plaintiff's allegations that XIFAXAN® was sold for several years, and therefore reduced to practice, prior to the critical date. *See Vanmoor*, 201 F.3d at 1366.

[4] Plaintiff asks this Court to take notice of the publicly available information on the FDA's website indicating that, between 2015 and 2017, Defendants sought and received FDA approval for changes to their XIFAXAN® product or manufacturing process. (Opp. Br. at 4). However, as Defendants point out, unless extraneous matters are "integral to or relied upon in the complaint[,]" such matters should not be considered by the Court. (Reply at 6 (quoting *In re Burlington Coat Factory Sec. Litig.*, 114 F.3d 1410, 1426 (3d Cir. 1997))).

are not free to flout the requirement of proving invalidity by clear and convincing evidence by asserting a 'practicing prior art' defense to literal infringement under the less stringent preponderance of the evidence standard." (Opp. Br. at 11 (quoting *Tate*, 279 F.3d at 1367)). However, this argument ignores that, under *Vanmoor* and *Evans Cooling*, a defendant may satisfy its burden through the plaintiff's own allegations.

Accordingly, the Court dismisses the Complaint but does so without prejudice because facts not yet alleged may support the plausible inference that the two forms of XIFAXAN® are distinct under *Tate*. Defendants argue that any amendment to the existing Complaint would be sought in bad faith because it would contradict facts alleged in the Complaint. (Reply at 10). But even assuming contradictory facts would be required, and it is not clear they would be, amended pleadings may contradict prior pleadings even if for the purpose of surviving a renewed motion to dismiss. *See W. Run Student Hous. Assocs. v. Huntington Nat'l Bank*, 712 F.3d 165, 172 (3d Cir. 2013).

IV. CONCLUSION

For the foregoing reasons, Defendants' motion to dismiss (D.E. No. 33) Plaintiff's Complaint is **GRANTED**. Plaintiff's Complaint is dismissed ***without prejudice***. An appropriate Order accompanies this Opinion.

Date: August 17, 2022

Hon. Esther Salas, U.S.D.J.